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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,531	03/29/2001	Eugenia Wang	UNLV 1010	3924
24350	7590	11/24/2004	EXAMINER	
STITES & HARBISON, PLLC 400 W MARKET ST SUITE 1800 LOUISVILLE, KY 40202-3352			SISSON, BRADLEY L	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/820,531	WANG, EUGENIA
	Examiner	Art Unit
	Bradley L. Sisson	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent-term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 August 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 34-36,38-40 and 42-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 34-36,38-40 and 42-54 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Workgroup 1630, Art Unit 1634, and has been docketed to Primary Examiner Bradley L. Sisson.

Specification

2. The disclosure is objected to because of the following informalities:
3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
4. The specification has been found to contain representations of nucleic acids sequences that are not accompanied with a SEQ ID NO.
5. Appropriate correction is required.

Claim Objections

6. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.
7. A claim, which depends from a dependent claim, should not be separated by any claim that does not also depend from said dependent claim. It should be kept in mind that a dependent

claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 34-36, 38-40, and 42-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; see also *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); *In re Gosteli*, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572.

10. For convenience, claims 34, 35, and 36, the only independent claims under consideration, are reproduced below.

34. (previously presented) A method for screening for genes whose expression is altered by disease, age, or exogenous agent, comprising:

screening a sample microarray comprising genes from a library, cells or animal exposed to the disease, age or exogenous agent, wherein expression of all of the genes is under control of the same regulatory element; and

comparing the expression of the genes to expression of control genes from a library, cells or animal not exposed to the disease, age or exogenous agent.

35. (currently amended) The method of claim 34 A method for screening for genes whose expression is altered by disease, age, or exogenous agent, comprising:

screening a sample microarray comprising genes from a library, cells or animal exposed to the disease, age or exogenous agent, wherein expression of all of the genes is under control of the same regulatory element; and

comparing the expression of the genes to expression of control genes from a library, cells or animal not exposed to the disease, age or exogenous agent;

wherein the microarray further comprises control genes that are not under the control of the same regulatory element.

36. (currently amended) The method of claim 34-A method for screening for genes whose expression is altered by disease, age, or exogenous agent, comprising:
screening a sample microarray comprising genes from a library, cells or animal exposed to the disease, age or exogenous agent, wherein expression of all of the genes is under control of the same regulatory element; and
comparing the expression of the genes to expression of control genes from a library, cells or animal not exposed to the disease, age or exogenous agent;
wherein the regulatory element is selected from the group of regulatory elements consisting of osmotic response element, retinoic acid response element, conserved proximal sequence element, vitamin D response element, sterol response element, TNF-alpha response element, serum response element, cAMP response element, antioxidant response element, glucocorticoid modulatory element, gonadotropin-releasing hormone-response element, pheromone response element, insulin response element, interferon consensus response element, estrogen response element, hypoxia response element, E2F transcription factor, xenobiotic response element, endoplasmic reticulum stress response element, iron-response element, androgen response element, stress response element, RAS-responsive element binding protein 1, and transforming growth factor, beta-1 response element.

11. For purposes of examination, the claimed method has been construed as encompassing the use of a "microarray" where the array comprises an infinite number of "genes," that said genes can be from any number of animals, and that the are full length sequences, comprising upstream and down stream regulators, exons as well as introns. Said "genes," have also been construed as encompassing genes which work in a feedback mechanism or work in a cascade arrangement.

12. Said claims have also been construed as encompassing the non-exposure of the "control genes" to any "age" or "exogenous agent." The aspect of not exposing a "control gene" to "age" has been construed as encompassing one suspending time. Said "exogenous agent" has also been construed as encompassing air, light, any temperature, pressure, gravity, etc. (See rejection under 35 USC 101, *infra*.)

13. A review of the disclosure finds but one example:

Example 1 : Selection of Primers.

14. In accordance with claim 34, one is to compare the expression of genes on a microarray to "control genes from a library." While the "control genes" are to be "from" a library, the claim has been interpreted as encompassing performing the comparison where the "control genes" are in cells and/or animals.

15. A review of the specification fails to locate a full clear, and concise description of the claimed invention so as to reasonably suggest that applicant was in possession of same at the time of filing. While applicant has made reference to various websites, the material found at those site, be it presently or at the time of filing, have not been incorporated by reference and as such, these sites cannot now be relied upon for satisfaction of the written description, enablement, or best mode requirements of 35 USC 112, first paragraph.

It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43

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USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at

1966:

Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

16. For the above reasons, and in the absence of convincing evidence to the contrary, claims 34-36, 38-40, and 42-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

17. Claims 34-36, 38-40, and 42-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth

as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

18. It is well settled that one cannot enable that which they do not yet possess. As presented above, the specification has not been found to contain an adequate written description of the invention such that it reasonably suggests that applicant was in possession of the invention at the time of filing. Accordingly, and in the absence of convincing evidence to the contrary, claims 34-36, 38-40, and 42-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

19. As noted above, the claimed methods have been interpreted as performing a comparison between "a sample microarray comprising genes from a library" with "control genes from a library" which are not exposed to "age" or "exogenous agent." A review of the specification has not been found to provide a reproducible procedure where by one can suspend time, nor be able to block any and all exogenous agents. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

" '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); see also *Amgen Inc. v. Chugai Pharm. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').

"Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

"It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research.

(Emphasis added)

20. The claimed invention relates directly to matters of physiology and chemistry, which are inherently unpredictable and as such, require greater levels of enablement. As noted in *In re Fisher* 166 USPQ 18 (CCPA, 1970):

In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

21. In view of the breadth of scope claimed, the limited guidance provided, the unpredictable nature of the art to which the claimed invention is directed, and in the absence of convincing

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evidence to the contrary, claims 34-36, 38-40, and 42-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

22. Claims 34-36, 38-40, and 42-54 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The claimed method is to result in the generation of data relating to the expression of genes in response to exposure to "disease, age, or exogenous agent." The mere generation of data has not been shown to result in either a specific and substantial utility or a well-established utility.

23. It matters not whether the claim is drawn to a product or process; the claim must be drawn to an invention that satisfies the utility requirements as set forth under 35 USC 101 and as further developed in the Utility Guidelines. In support of this position, attention is directed to *Brenner, Comr. Pats. v. Manson*, 148 USPQ 689 (US SupCt 1966).

Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, 22 without compensating benefit to the public. The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point-where specific benefit exists in currently available form- there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

* * *

We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product.²⁴ That proposition seems to us little more than an attempt to evade the impact of the rules which concededly govern patentability of the product itself.

This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something "useful," or that we are blind to the prospect that what now seems without "use" may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.

24. Claims 34-36, 38-40, and 42-54 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 101

25. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

26. Claims 34-36, 38-40, and 42-54 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. As presently worded, the claimed methods encompass embodiments that have been construed as requiring the stopping of time as well as the non-exposure of control genes to any and all exogenous agents. The record does not describe in a reproducible manner how time can be stopped. The specification does not describe how "control genes" can not be exposed to any and all "exogenous agents," which for purpose of

examination have been construed as encompassing temperature, gravity, pressure, any pH value of the surrounding medium, if any, and stress, be it physiological, environmental and/or psychological, etc.

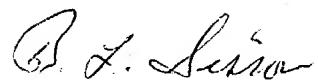
Conclusion

27. Rejections and/or objections that appeared in the last Office action and that were not repeated hereinabove have been withdrawn.
28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.
29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
23 November 2004